UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

NO. 1:11-md-02242-RWZ

IN RE: PROGRAF ANTITRUST LITIGATION

MEMORANDUM OF DECISION

December 17, 2013

S E A L E D

ZOBEL, D.J.

Plaintiffs in this consolidated antitrust action are indirect purchasers of Prograf, a branded prescription immunosuppressant used in organ transplant patients. They are suing Astellas Pharma US, Inc. ("Astellas"), a pharmaceutical manufacturer and maker of Prograf, for filing an allegedly baseless citizen petition with the Food and Drug Administration ("FDA") with the sole intent of foreclosing market entry by generic competitors and improperly extending its monopoly. Plaintiffs seek to certify a class of consumers and third-party payors ("TPPs")[1] under antitrust, consumer protection, and unjust enrichment laws of numerous states.

After a hearing and careful consideration of the parties' voluminous submissions, I find that plaintiffs have not satisfied the requirements of Fed. R. Civ. P. 23(b)(3). Accordingly, their motion for class certification (Docket # 153) is DENIED.

[1] Third-party payors include health benefit plans, health insurers, and self-insured employers.

I. Background[2]

A. Astellas and Prograf

Astellas manufactures, markets, and sells Prograf, a brand name prescription immunosuppressant used to prevent organ rejection by patients who have had liver, kidney, or heart transplants. The main active ingredient in Prograf is tacrolimus. The FDA approved Prograf 1 mg and 5 mg capsules and injections in 1994, and 0.5 mg capsules in 1998. Astellas's patent for Prograf expired on April 8, 2008.

B. Drug Approval Process

Under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301–392, manufacturers who wish to market a new drug product must obtain FDA approval by filing a New Drug Application ("NDA"). An NDA must contain specific data concerning the safety and effectiveness of the drug. In 1984, Congress passed the Hatch-Waxman Amendments that modified the FDCA by creating a streamlined process for bringing generic drugs to market without the need to file lengthy and costly NDAs with the FDA. Manufacturers of generic drugs may submit an Abbreviated New Drug Application ("ANDA"), which incorporates and relies on the scientific findings of safety and effectiveness established by the brand name drug's original NDA. To receive FDA approval, a prospective generic manufacturer must demonstrate that the generic drug it seeks to market is "bioequivalent" to the brand name drug, meaning that the generic drug has essentially the same active ingredient, dosage form, route of administration, and strength as its branded counterpart.

[2] The following descriptions and allegations are drawn from plaintiffs' amended complaint.

Federal regulations allow individuals or entities to express concerns to the FDA about safety, scientific, or legal issues regarding a product anytime before or after its market entry by means of a citizen petition. Such a petition may request that the FDA take, or refrain from taking, any administrative action. 21 CFR § 10.30. The FDA commissioner must respond to, but not necessarily resolve, each citizen petition within 180 days of receipt. Plaintiffs assert that, because reviewing and responding to a citizen petition is a resource-intensive and time-consuming task, the FDA typically takes much longer than 180 days to issue a final response.

C. Sandoz and Astellas's Citizen Petition

On December 28, 2006, Sandoz, Inc. ("Sandoz"), a generic pharmaceutical manufacturer, filed an ANDA to market and sell tacrolimus capsules in 0.5 mg, 1 mg, and 5 mg dosages. On September 21, 2007, while Sandoz's application was still pending, Astellas filed a citizen petition requesting, among other things, changes in bioequivalence testing requirements for tacrolimus products. Plaintiffs allege that the FDA maintained a well-known practice at that time of withholding ANDA approval until after its consideration of and response to relevant citizen petitions was complete.[3]

Nearly two years later, on August 10, 2009, the FDA denied nearly all the relief requested in Astellas's citizen petition and approved Sandoz's ANDA for generic tacrolimus. Sandoz brought its generic tacrolimus products to market the following

[3] On September 28, 2007, less than a week after Astellas filed its petition, the FDA Amendments Act of 2007, 21 U.S.C. § 355(q), went into effect. The amendments, which apply only to citizen petitions filed on or after September 27, 2009, require the FDA to not delay approval of a pending ANDA because of a citizen petition unless such a delay is necessary to protect the public health. The amendments also permit the FDA to summarily dismiss citizen petitions whose primary purpose is to delay generic competition.

day.[4]

D. Procedural History

Plaintiffs New Mexico United Food and Commercial Workers Union's and Employers' Health and Welfare Trust Fund ("NMUFCW"), Louisiana Health Service Indemnity Company d/b/a Bluecross/Blueshield of Louisiana ("BCBSLA"), Janet M. Paone ("Paone"), and Judith Carrasquillo ("Carrasquillo") (collectively, "plaintiffs"), each initiated suits against Astellas in late 2011, and following consolidation, filed an amended class action complaint on March 27, 2012. They allege that Astellas, by filing a baseless "sham" citizen petition with the FDA, sought to improperly delay market entry by generic competitors and extend its monopoly on tacrolimus drugs. Plaintiffs claim that absent Astellas's exclusionary conduct, generic tacrolimus would have entered the market in April 2008 (at patent expiration) instead of in August 2009. The complaint alleges that, as a result, consumers and TPPs were prevented from purchasing or reimbursing for less-expensive generic tacrolimus and were forced to pay supra-competitive prices for branded Prograf.[5]

Plaintiffs bring state law claims for the violation of antitrust and/or consumer protection statutes of 27 jurisdictions and common law unjust enrichment under the laws of 32 jurisdictions. They move to certify an indirect purchaser class of:

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[4] Astellas unsuccessfully sought a temporary restraining order against the FDA to stay the approval of Sandoz's generic. The FDA subsequently approved ANDAs for several other generic versions of tacrolimus in 2010.

[5] A related antitrust lawsuit against Astellas, alleging the same misconduct, has been filed by direct purchasers of Prograf under § 2 of the Sherman Act. Upon Astellas's stipulation, I allowed the direct purchaser plaintiffs' motion for class certification on April 23, 2013 (Docket # 216).

All persons or entities in the United States and its territories who purchased, paid for, and/or reimbursed for some or all of the purchase price for branded Prograf capsules in Arizona, California, Delaware, District of Columbia, Florida, Georgia, Idaho, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Dakota, Tennessee, Vermont, West Virginia, and Wisconsin, for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries, other than for resale, at any time during the period from April 15, 2008, until December 31, 2010.

The following persons or entities are excluded from the proposed Class:

a. Defendant and its officers, directors, management, employees, subsidiaries, and affiliates;

b. all governmental entities (except for government funded employee benefit plans);

c. all persons or entities who purchased Prograf for purposes of resale or directly from Defendant or its affiliates;

d. fully insured health plans—*i.e*., plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members;

e. any "flat co-pay" consumers whose purchases were paid in part by a third-party payor and whose co-payment share of the purchase price did not vary between brand-name and generic drug purchases;

f. individual consumers whose only purchases of Prograf were subsidized through the Astellas Prograf Assistance Program (PAP) and/or the Astellas Prograf Value Card Program;[6]

g. the judges in this case and any members of their immediate families.

[6] Under PAP, Astellas paid the entire prescription cost for uninsured or underinsured consumers who qualified. Similarly, under the Value Card ("VC") Program, Astellas paid the consumer's copayment or coinsurance costs such that consumers paid little or no copay.

Plaintiffs' Proposed Order (Docket # 153, Ex. 1). Astellas opposes certification. A hearing on plaintiffs' motion for class certification was held on August 6, 2013.

II. Legal Standard

Federal Rule of Civil Procedure 23 governs class certification. The district court may only certify a class after a "rigorous analysis of the prerequisites established by Rule 23." Smilow v. Sw. Bell Mobile Tel. Sys., 323 F.3d 32, 38 (1st Cir. 2003); see also Comcast Corp. v. Behrend, 133 S. Ct. 1426, 1432 (2013). Under Rule 23(a), a party seeking class certification must show that:

> (1) the class is so numerous that joinder of all members is impracticable;
>
> (2) there are questions of law or fact common to the class;
>
> (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and
>
> (4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a). These four requirements are known as numerosity, commonality, typicality, and adequacy. See Smilow, 323 F.3d at 38.

In addition, the party seeking certification must show that one of the requirements of Rule 23(b) is met. Plaintiffs seek to proceed under Rule 23(b)(3), which allows a class action if "the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3).

III. Discussion

A. Ascertainability

As a preliminary matter, the proposed class must satisfy an implicit requirement in Rule 23 of ascertainability, i.e., that "determining whether a particular individual is a member of the class is administratively feasible." Shanley v. Cadle, 277 F.R.D. 63, 67 (D. Mass. 2011); see also 7A Charles Alan Wright et al., Federal Practice & Procedure (Civil) § 1760 (3d ed. 2013). All class members need not be identified at the outset; rather, the class is ascertainable if it can be determined by "stable and objective factors." Kent v. SunAmerica Life Ins. Co., 190 F.R.D. 271, 278 (D. Mass. 2000).

Astellas claims plaintiffs' proposed class is not ascertainable because individualized investigation would be required to identify potential members. It takes issue not so much with the class definition per se, but with its exclusions – namely, the exclusion of fully-insured health plans, "flat co-pay" consumers, and consumers whose only purchases of Prograf were subsidized through Astellas's assistance programs. Astellas argues that these indirect purchasers would be impossible to identify (and therefore exclude from the class) without extensive inquiry into individual pharmacy and benefits records.[7]

Astellas does not dispute, however, that the criteria for membership in the proposed class are objective, based upon whether an indirect purchaser paid or reimbursed for Prograf during a specified time period in the delineated jurisdictions.

[7] Astellas also asserts an inability to differentiate uninjured indirect purchasers from possibly injured ones from *within* the class as defined. Such arguments pertain more to whether plaintiffs can adequately demonstrate class-wide injury (a predominance inquiry) than to ascertainability of the class.

"The presence of such an objective criterion overcomes the claim that the class is unascertainable." Matamoros v. Starbucks Corp., 699 F.3d 129, 139 (1st Cir. 2012). As for the exclusions cited by Astellas, they, too, are based on objective criteria: either a consumer had only flat co-pays between branded and generic drugs, or she did not; either a patient's only Prograf purchases were subsidized by Astellas, or they were not; either a health plan ultimately bore the costs of Prograf purchases, or it did not. Consumer class members can sign affidavits under penalty of perjury certifying that they paid for at least one Prograf prescription that was not subject to a flat co-pay or subsidy, and TPPs presumably would know, or would have records showing, whether they ever paid for a Prograf purchase. See Donovan v. Philip Morris USA, Inc., 268 F.R.D. 1, 9 (D. Mass. 2010) (rejecting ascertainability concerns where factors at issue – smoking history and a diagnosis of lung cancer – were objective criteria and could be certified through affidavits or doctors' letters).

Astellas's complaints really amount to concerns about the administrative burden of determining class members, which – while valid – are issues of manageability, not ascertainability. The proposed class is ascertainable.

B. Rule 23(a) Requirements[8]

1. Numerosity

Under Rule 23(a)(1), the numerosity requirement is met if "the class is so numerous that joinder of all members is impracticable." Here, plaintiffs estimate that

[8] Astellas does not dispute that the numerosity, commonality, and typicality requirements have been met.

class members from numerous states will number in the tens of thousands. Numerosity is easily satisfied.

2. Commonality

Commonality asks whether there are "questions of law or fact common to the class." Fed. R. Civ. P. 23(a)(2). It requires the party seeking certification to show a "common contention . . . that is capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke." Wal-Mart Stores, Inc. v. Dukes, 131 S. Ct. 2541, 2551 (2011). Even a single common question can be enough to satisfy Rule 23(a)(2). Id. at 2556.

Plaintiffs advance a number of common questions, the answers to which are "apt to drive the resolution of the litigation." Id. at 2551 (quoting Richard A. Nagareda, Class Certification in the Age of Aggregate Proof, 84 N.Y.U. L. Rev. 97, 132 (2009)). These include: "(1) whether Astellas delayed or prevented generic manufacturers from coming to market in the United States; (2) whether Astellas's citizen petition to FDA during FDA's review of ANDAs for generic tacrolimus was objectively baseless; (3) whether Astellas unlawfully maintained monopoly power by delaying generic entry; (4) whether direct proof of Astellas's monopoly power is available and, if so, whether it is sufficient to prove Astellas's monopoly power without the need to also define a relevant market; (5) to the extent a relevant market or markets must be defined, what that definition is or what those definitions are; and (6) whether Astellas's conduct caused injury to Plaintiffs and Class members and, if so, the appropriate measure of damages."

Plaintiffs' Brief ("Pl. Br.") (Docket # 155) at 16. Plaintiffs have met the commonality requirement.

3. Typicality

The typicality requirement is satisfied if "the claims or defenses of the representative parties are typical of the claims or defenses of the class." Fed. R. Civ. P. 23(a)(3). The representative plaintiffs are sufficiently typical if their claims "arise from the same course of conduct and are based on the same legal theory as the class claims." Evergreen Ultra Short Opportunities Fund Securities Litigation, 275 F.R.D. 382, 389 (D. Mass. 2011). Here, the claims of each named plaintiff and those of the class arise from the same course of conduct (Astellas's allegedly anti-competitive actions) and are based upon the common legal theories of monopolization, deceptive trade practices, and unjust enrichment. All plaintiffs and members of the proposed class assert that Astellas's alleged misconduct resulted in an overcharge for tacrolimus products or unjust enrichment at their expense. Accordingly, I find the typicality requirement satisfied.

4. Adequacy of Representation

Adequacy of representation requires that "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). This entails a two-part showing: "(1) the attorneys representing the class must be qualified and competent; and (2) the class representatives must not have interests antagonistic to or in conflict with the unnamed members of the class." Andrews v. Bechtel Power Corp., 780 F.2d 124, 130 (1st Cir. 1985). Astellas does not challenge the qualifications of

proposed class counsel. Indeed, plaintiffs' lead counsel have extensive experience in pharmaceutical class action lawsuits and have vigorously and capably represented the putative class throughout the course of this litigation.

Astellas does raise objections to three of the named plaintiffs which I will treat as adequacy arguments. Astellas charges that NMUFCW and the two consumer plaintiffs, Paone and Carrasquillo, were not injured and therefore cannot properly serve as class representatives. It bases that conclusion on an analysis of plaintiffs' Prograf and generic tacrolimus purchases. Plaintiffs, however, counter with their own analysis and evidence which purport to show that NMUFCW, Paone, and Carrasquillo were harmed.

If in fact the named plaintiffs suffered no injury, it could create an internal conflict within the class. But Astellas's arguments, which depend on premises and assumptions that plaintiffs dispute, do not convince me, at least at this stage, that plaintiffs have interests so antagonistic to the other class members that they could not adequately represent the class. See Matamoros, 699 F.3d at 138 ("To forestall class certification the intra-class conflict must be so substantial as to overbalance the common interests of the class members as a whole."); George v. National Water Main Cleaning Co., 286 F.R.D. 168, 177 (D. Mass. 2012) (defendants' argument that named plaintiffs may have benefitted from the alleged illegal conduct "makes assumptions about the merits that are not now before the Court"). The named plaintiffs are part of the putative class, allege the same injury as the class members, and thus far have shown that their interests align with those of the absent class members. I am satisfied that the adequacy requirement has been met.

C. Rule 23(b) Requirements

Having fulfilled the prerequisites of Rule 23(a), plaintiffs must also overcome the hurdles of Rule 23(b)(3), which authorizes a class action where "the questions of law or fact common to class members predominate over any questions affecting only individual members, and . . . a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). Certifying a class under Rule 23(b)(3) requires "a close look at the case before it is accepted as a class action." In re New Motor Vehicles Canadian Export Antitrust Litig., 522 F.3d 6, 18 (1st Cir. 2008) (quoting Amchem Prods. v. Windsor, 521 U.S. 591, 615 (1997)).

Astellas argues that plaintiffs cannot satisfy Rule 23(b)(3) for two primary reasons: demonstrating antitrust impact to class members will require individualized inquiries as opposed to common evidence, and the diversity of state laws at issue in this case precludes certification. I address these contentions in reverse order.

1. Variation in State Laws[9]

Plaintiffs bring common law unjust enrichment claims under the laws of 32 different jurisdictions, as well as statutory antitrust and consumer protection claims under the laws of 27 of those jurisdictions.[10] Plaintiffs insist that the relevant state laws

[9] The parties agree that under Massachusetts choice-of-law rules, the court must apply the law of the state where each consumer purchased tacrolimus. See In re Relafen Antitrust Litigation, 221 F.R.D. 260 at 277-78 (D. Mass. 2004).

[10] Plaintiffs' consumer protection claims are closely linked to their antitrust claims and are premised on three main theories of liability: (1) the state consumer protection statute "borrows" violations of other antitrust statutes as the basis for a claim; (2) Astellas's monopolistic conduct amounts to "unfair methods of competition" or "unfair" or "unconscionable" acts or practices prohibited by the consumer protection law; and (3) Astellas engaged in "deceptive" conduct aimed at the FDA or the federal courts in violation of the consumer protection statute. See Plaintiffs' Reply Brief ("Pl. Rep. Br.") (Docket # 272) at 21-22 .

are substantially similar and can be applied together. Astellas, in turn, argues that there are significant differences among the state laws that make class treatment impracticable and unmanageable. The parties' arguments involve overlapping concerns about predominance and superiority.

Certification of a multi-state class action presents numerous, but not insurmountable, substantive and practical challenges. The key inquiry here is "not whether the laws of multiple states are identical, but whether the Court can manage the differences." Overka v. American Airlines, Inc., 265 F.R.D. 14, 20 (D. Mass. 2010). While uniformity of state laws is not required under Rule 23(b)(3), "variations in state law may swamp any common issues and defeat predominance." In re Pharmaceutical Industry Average Wholesale Price Litigation, 230 F.R.D. 61, 82 (D. Mass. 2005) (quoting Klay v. Humana, Inc., 382 F.3d 1241, 1261 (11th Cir. 2004)). Manageability concerns have also prompted courts in some cases to find that a "class action is not a superior method for adjudicating" claims under the laws of multiple jurisdictions. In re Celexa and Lexapro Marketing and Sales Practices Litigation, 291 F.R.D. 13, 19 (D. Mass. 2013). "Courts should look at how issues are likely to play out in the context of the case to see what individual issues are likely to arise, and what state law differences are irrelevant and may be ignored." In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. at 84.

Plaintiffs provided the court with a detailed state-by-state review of the antitrust and consumer protection laws at issue.[11] They claim that each statute prohibits monopolization, provides a cause of action for indirect purchasers, and requires the same general elements for liability. Moreover, plaintiffs note that most of the relevant states have harmonization provisions or judicial precedent requiring that the state statutes be interpreted in accordance with applicable federal law.

Astellas responds with its own analysis highlighting various differences among the state antitrust and consumer protection statutes. Such differences include whether businesses can bring claims as plaintiffs; whether proof of reliance is required;

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[11] **Arizona**: Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. § 44- 1401, *et seq*. and the Constitution of the State of Arizona, Article 14, § 15; **California:** California Unfair Competition Act, Cal. Bus. & Prof. Code § 17200, *et seq*.; **Delaware:** 6 Delaware Code Ann. § 2511, *et seq*.; **District of Columbia:** District of Columbia Antitrust Act, D.C. Code § 28-4501, *et seq*. and District of Columbia's Consumer Protection Procedures Act, D.C. Code Ann. § 28-3901, *et seq*.; **Florida:** Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. § 501.201, *et seq*.; **Iowa:** Iowa Competition Law, Iowa Code §§ 553.4, 553.5; **Maine:** Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, § 1101, *et seq*. and Maine's Unfair Trade Practices Act, Me. Rev. Stat. Ann., tit. 5, § 207, *et seq*.; **Massachusetts:** Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A, § 11; **Michigan:** Michigan Antitrust Reform Act, Mich. Comp. Laws § 445.771, *et seq*.; **Minnesota:** Minnesota Antitrust Law of 1971, Minn. Stat. § 325D.49, *et seq*. and Minnesota Consumer Fraud Act, Minn. Stat § 325F.67, *et seq*.; **Mississippi:** Miss. Code Ann. § 75-21-1, *et seq*.; **Missouri:** Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.025; **Nebraska:** Ne. Rev. Stat. § 59-801, *et seq*. and Nebraska's Consumer Protection Act, Neb. Rev.
Stat. § 59-1601 *et seq*.; **Nevada:** Nevada Unfair Trade Practices Act, Nev. Rev. Stat. § 598A.010, *et seq*. and Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. § 598.0903, *et seq*.; **New Hampshire:** New Hampshire state consumer protection laws, N.H. Rev. Stat. § 358-A, *et seq*.; **New Mexico:** New Mexico Antitrust Act, N.M. Stat. Ann. § 57-1-1, *et seq*. and New Mexico Unfair Practices Act, N.M. Stat. Ann. § 57-12-1, *et seq*.; **North Carolina:** North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. § 75-1, *et seq*.; **North Dakota:** North Dakota Antitrust Act, N.D. Cent. Code § 51- 08.1-01, *et seq*.; **Oregon:** Oregon's antitrust laws, Or. Rev. Stat. §§ 646.780, *et seq*.; **Pennsylvania:** Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat. Ann. § 201-1, *et. seq*.; **Puerto Rico:** Puerto Rico Antitrust Act, Puerto Rico Code 10 LPRA § 257, *et seq*.; **Rhode Island:** Rhode Island's eceptive Trade Practices Act, R.I. Gen. Laws § 6-13.1.1, *et. seq*.; **South Dakota:** South Dakota's antitrust law, S.D. Codified Laws § 37-1- 3, *et seq*.; **Tennessee:** Tennessee Trade Practices Act, Tenn. Code Ann. § 47-25-101, *et seq*.; **Vermont:** Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, § 2451, *et seq*.; **West Virginia:** West Virginia Antitrust Act, W. Va. Code § 47-18-1; **Wisconsin:** Wisconsin Antitrust Act, Wis. Stat. § 133.01, *et seq*.

variability regarding the nature and level of scienter and intent to deceive; variability regarding the nature of fraud or deception required; demand or notice provisions; requirements that the actionable misconduct occur within the state; whether a Hanover Shoe[12] "pass-on defense" is permitted; and the availability of different types of damages. Astellas also contends that unilateral monopolization is not actionable in Tennessee, and that in some jurisdictions that follow Illinois Brick[13] indirect purchasers may not pursue antitrust claims under the state's consumer protection act.

Such differences in the applicable antitrust and consumer protection laws are not so significant as to preclude a finding of predominance. Nearly all the state antitrust laws track the language and scope of the Sherman Act, while harmonization provisions instruct that consumer protection statutes be construed in accordance with federal interpretations of the Federal Trade Commission Act, which declares unlawful "unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce," 15 U.S.C. § 45. Plaintiffs correctly point out that many of the alleged variations identified by Astellas are not relevant to the claims brought in this case. Reliance and scienter, required by some consumer protection statutes, are unlikely to be material or require individualized inquiry where the basis for

[12] In Hanover Shoe v. United Shoe Machine, 392 U.S. 481 (1968), the Supreme Court held that a defendant in an antitrust action may not assert, as a defense, that the plaintiff was not injured by the antitrust violation because it "passed on" the overcharges it suffered to its customers.

[13] In Illinois Brick Co. v. Illinois, 431 U.S. 720 (1977), the Supreme Court held that indirect purchasers lack standing to sue for antitrust violations under federal law. In the wake of that decision, some states enacted so-called "Illinois Brick repealer statutes" permitting state law antitrust damage actions by or on behalf of indirect purchasers. Other states allow indirect purchasers to pursue similar claims under their consumer protection acts.

plaintiffs' claims is not fraudulent conduct or misrepresentations directed at them, but rather Astellas's unlawful monopolistic practices and its deceptive conduct directed at the FDA , which will depend on evidence common to all class members. The Hanover Shoe pass-on defense, typically invoked against direct purchasers, is also of little relevance here, where class members are "final" purchasers who did not resell Prograf. Discrete issues of law, such as standing and the effect of Illinois Brick in specific jurisdictions, can be resolved by the court in summary judgment proceedings.[14] To the extent that some jurisdictions may require distinctive elements to establish liability, special questions can be submitted to the jury on whether such elements were satisfied. Finally, plaintiffs propose to manage variations in the damages available under each state's laws through a detailed trial plan in which special jury findings will be used to establish aggregate damages for each jurisdiction. I find that plaintiffs have demonstrated sufficient commonality among the relevant antitrust and consumer protection laws.[15] See In re Terazosin Hydrochloride Litig., 220 F.R.D. 672, 695 (S.D. Fla. 2004) (finding predominance under antitrust laws of 17 jurisdictions because "the

[14] The question of whether unilateral monopolization claims may be brought under Tennessee law can also be addressed via summary judgment practice. I note that while the language of the Tennessee Trade Practices Act does not by its terms include unilateral conduct, the Tennessee Court of Appeals, without addressing the issue, allowed a claim of monopolization by a single firm to go forward in Sherwood v. Microsoft Corp., No. M2000-01850-COA-R9-CV, 2003 WL 21780975 (Tenn. Ct. App. July 31, 2003).

[15] Notwithstanding this finding, two topics merit special comment. First, plaintiffs have not alleged compliance with any relevant notice provisions under the state statutes. Second, it appears that there is no right to bring a class action under Mississippi law. Am. Bankers Ins. Co. of Fla. v. Booth, 830 So. 2d 1205, 1214 (Miss. 2002) ("[t]he rule is that Mississippi does not permit class actions"). Both issues may warrant excluding potential class members in those jurisdictions. See In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. at 84-85 (excluding consumers in states where class actions are not permitted and plaintiffs did not show compliance with notice provisions).

essential elements of Indirect Purchaser Plaintiffs' antitrust claims do not vary significantly from state-to-state, and they are susceptible to proof using common evidence."); In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. at 85 (finding that common legal and factual issues predominated under the consumer protection laws of all but 9 states).

The parties raise similar arguments with respect to unjust enrichment laws. Plaintiffs argue that common law claims for unjust enrichment are substantially identical across all the relevant jurisdictions.[16] They assert that all of their unjust enrichment claims share the same essential elements: (1) enrichment of the defendant at the expense of the plaintiff; (2) that the defendant retained the benefit; and (3) that retention of the benefit without payment would create an injustice. See Plaintiffs' State by State Unjust Enrichment Laws (Docket # 155, Ex. 2) (listing elements of unjust enrichment claims in each jurisdiction). Astellas does not dispute these core elements, but claims that such "surface similarities" mask material variations in the laws of different states. Chief among them are different standards for privity between plaintiffs and defendants;[17] varying requirements about the nature of the conduct[18] and the intent

[16] Arizona, California, Delaware, District of Columbia, Florida, Georgia, Idaho, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Dakota, Tennessee, Vermont, West Virginia, and Wisconsin.

[17] Florida and Massachusetts require a direct relationship between plaintiff and defendant, see American Safety Ins. Serv., Inc. v. Griggs, 959 So. 2d 322, 331 (Fla. Dist. Ct. App. 2007), and Blake v. Prof'l Coin Grading Serv., 898 F. Supp. 2d 365, 390 (D. Mass. 2012), while other states require no privity or are inconsistent/silent on the issue.

[18] For example: Arizona requires an "absence of justification" for the benefit conferred. Community Guardian Bank v. Hamlin, 898 P.2d 1005, 1008 (Ariz. Ct. App. 1995). North Carolina requires that the benefit not be "conferred gratuitously or by an interference in the affairs of another

or scienter required[19]; and whether adequate remedies at law (such as antitrust claims) preclude recovery.[20] Astellas also notes differences in the effect of Illinois Brick on indirect purchasers' ability to pursue unjust enrichment claims, the number of elements that make up a claim, and the basis and measure of recovery. In response, plaintiffs argue that many of the cited variations are minor and that material additional elements can be presented to the jury through a special verdict form.

There are numerous examples from the case law in support of both parties' positions. Compare, e.g., Overka, 265 F.R.D. at 20-21 (ruling that the unjust enrichment laws of 34 jurisdictions are "substantially common and the differences between them are manageable"), In re Relafen, 221 F.R.D. at 278-80 (certifying a multi-state settlement class for unjust enrichment claims in five states), and In re Terazosin Hydrochloride, 220 F.R.D. at 701 (rejecting argument that multi-state class was unmanageable because of substantial variations in unjust enrichment laws) with Faherty v. CVS Pharmacy, No. 09-CV-12102, 2011 WL 810178, at *5 (D. Mass. Mar. 9, 2011) (declining to certify class on unjust enrichment claims in 44 jurisdictions due to "the intricate nature of the task and the potential for juror confusion"), Spencer v. Hartford Financial Services Group, Inc., 256 F.R.D. 284, 305 (D. Conn. 2009) (finding that legal variations in unjust enrichment claims of 50 states defeated a finding of

party." Southeastern Shelter Corp. v. BTU, Inc., 572 S.E. 2d 200, 206 (N.C. 2002).

[19] Some jurisdictions – Florida, Kansas, Maine, Massachusetts, Missouri, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, and Wisconsin – require appreciation or knowledge of the benefit by the defendant.

[20] In Arizona, Iowa, Maine, Massachusetts, Minnesota, North Dakota, and Puerto Rico, unjust enrichment claims are only available where there is no adequate remedy at law.

predominance), and In re Conagra Peanut Butter Products Liability Litigation, 251 F.R.D. 689, 698 (N.D. Ga. 2008) ("The many differences among jurisdictions should prevent the Court from finding that common issues of law predominate on this [unjust enrichment] claim."). In the particular circumstances of this case, however, I am persuaded that plaintiffs have the better of the argument. "In all states, the focus of an unjust enrichment claim is whether the defendant was *unjustly* enriched." Powers v. Lycoming Engines, 245 F.R.D. 226, 231 (E.D. Pa.2007) (emphasis in original), rev'd on other grounds, 2009 WL 826842, 328 Fed. Appx. 121 (3d Cir. 2009). See also Cohen v. Chilcott, 522 F. Supp. 2d 105, 116 (D.C. Cir. 2007) ("Although Plaintiffs assert claims under the unjust enrichment laws of the fifty states, such claims may involve predominant common questions insofar as they all require a showing that Defendants were unjustly enriched at the expense of the Class Members. Moreover, the existence of minor differences in state law does not preclude the certification of nationwide classes."). I find that the same core elements form the basis for unjust enrichment claims in all the named jurisdictions and largely predominate over the various differences among them.[21]

2. Predominance of Common Questions of Law or Fact

The parties' arguments over certification center largely on the question of predominance. Predominance tests "whether proposed classes are sufficiently

[21] There are questions, not raised here, as to whether plaintiffs can assert unjust enrichment claims in states where applicable antitrust and consumer protection statues do not provide for an equitable remedy. See Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC, 737 F. Supp. 2d 380, 426 (E.D. Pa. 2010). Such issues, as well as the availability of unjust enrichment claims in Illinois Brick jurisdictions, are legal questions that can be resolved through summary judgment.

cohesive to warrant adjudication by representation." Amchem, 521 U.S. at 623. Common questions may predominate despite the existence of individual differences, as long as "a sufficient constellation of common issues binds class members together." Waste Mgmt. Holdings v. Mowbray, 208 F.3d 288, 296 (1st Cir. 2000). However, the predominance standard is "far more demanding" than the commonality requirement of Rule 23(a)(2). In re New Motor Vehicles, 522 F.3d at 20 (quoting Amchem, 521 U.S. at 624). Deciding what questions predominate requires the court to "formulate some prediction as to how specific issues will play out." Waste Mgmt., 208 F.3d at 298.

Evaluating predominance "begins, of course, with the elements of the underlying cause of action." Erica P. John Fund, Inc. v. Halliburton Co., 131 S. Ct. 2179, 2184 (2012). "Under both federal and state law, the essential elements of a private antitrust action are the same: proof of a violation by the defendant, a demonstration of injury to the plaintiff, and an approximation of the plaintiff's damages."[22] In re Relafen, 221 F.R.D. at 275. See also In re Wellbutrin XL Antitrust Litigation, 282 F.R.D. 126, 139 (E.D. Pa. 2011) (elements of plaintiffs' antitrust claims are "(1) a violation of the state antitrust laws and/or state consumer protection laws, (2) individual injury, and (3) measurable damages."). Plaintiffs' burden at the class certification stage is not to prove each of these elements; "Rule 23(b)(3) requires a showing that *questions* common to the class predominate, not that those questions will be answered, on the

[22] The analysis that follows applies equally to plaintiffs' consumer protection claims, which rely on the same theory and operative evidence as their antitrust claims. Similarly, plaintiffs' claims for unjust enrichment are based upon the same facts and proof underlying their antitrust and consumer protection claims. That is, in order to prove that it would be inequitable for Astellas to retain the benefit of class members' purchases, plaintiffs must show that such "enrichment" was the result of Astellas' unlawful anti-competitive conduct.

merits, in favor of the class." Amgen Inc. v. Connecticut Retirement Plans and Trust Funds, 133 S. Ct. 1184, 1191 (2013) (emphasis in original).

Plaintiffs assert, and Astellas does not dispute, that common issues predominate with respect to the first element, violation of antitrust law. I agree. The showing necessary to prove a violation in this case – the possession of monopoly power in the relevant market and the willful maintenance of that power through anti-competitive or exclusionary means – focuses entirely on Astellas' alleged conduct rather than that of individual class members and can be proven through evidence common to the class. See In re Relafen, 221 F.R.D. at 275 ("The alleged antitrust violation relates solely to [defendant's] conduct, and, as such, constitutes a common issue subject to common proof); In re Wellbutrin XL, 282 F.R.D. at 140 ("The issues of relevant market, monopoly power, and exclusionary conduct can be proven uses common, class-wide evidence because such issues focus on the defendants' conduct rather than individual class members.").

As for the third element, measurable damages, plaintiffs need not supply precise damage figures for each class member at the class certification stage; instead, they may present proof of class damages in the aggregate. See In re Pharm. Indus. Average Wholesale Price Litig., 582 F.3d 156, 197-98 (1st Cir. 2009). Here, plaintiffs propose to calculate aggregate damages for the entire class through the use of "yardstick" methodology, examined in more detail below, and allocate those damages

later to individual class members through a separate claims process.[23] While ultimate determinations regarding the amount of each class member's recovery will invariably depend on individualized inquiry, "predominance is not defeated by individual damages questions as long as liability is still subject to common proof." In re New Motor Vehicles, 522 F.3d at 28 (citations omitted).

But whether liability in this case is in fact subject to common proof is the primary quarrel between the parties. In contrast to antitrust violation and damages, predominance on the second element, a demonstration of injury or "antitrust impact," is the subject of vigorous and complex debate. "In antitrust actions, common issues do not predominate if . . . the fact of antitrust impact cannot be established through common proof." In re New Motor Vehicles, 522 F.3d at 20. See also In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 311-12 (3d Cir. 2008) (plaintiffs need not prove the element of antitrust impact at the certification stage, but must demonstrate that it is "capable of proof at trial through evidence that is common to the class rather than individual to its members."). Plaintiffs' theory of impact "must include some means of determining that each member of the class was in fact injured, even if the amount of each individual injury could be determined in a separate proceeding." In re New Motor Vehicles, 522 F.3d at 28.

In an overcharge case, impact is shown through proof that (1) the defendant charged more for its product than it would have but-for its antitrust violation; and (2)

[23] Plaintiffs also calculate unjust enrichment damages by applying yardstick methodology to data on sales, profits, and costs.

class members paid for the product at the illegally inflated price. In re Terazosin Hydrochloride, 220 F.R.D. at 696. Plaintiffs assert that Astellas's alleged monopolization of the tacrolimus market resulted in two types of overcharge injuries to class members. First, they contend that consumers and TPPs were limited to purchasing or reimbursing for branded Prograf prescriptions during the class period instead of having the opportunity to pay for cheaper generic tacrolimus. Second, they claim that class members were also overcharged for branded Prograf, which was more expensive during the class period than it would have been absent Astellas's exclusionary conduct.

a. Plaintiffs' Proof of Antitrust Impact

In support of their arguments, plaintiffs submitted an expert report from Dr. Meredith Rosenthal, who was asked to "opine on whether the proposed Class would have been impacted economically by the alleged foreclosure of generic entry by [Astellas] and if so whether there is a scientifically acceptable methodology by which such impact could be measured." Rosenthal Decl. (Docket # 293), Part I.[24] Dr. Rosenthal explains that, in the pharmaceutical industry, generic entry generally leads to "much more vigorous price competition that will drive down prices for a given chemical entity." Id. at ¶ 20. Price competition is also influenced by TPPs, who adopt various cost control mechanisms – including tiered formularies, generic substitution

[24] Dr. Rosenthal is a Professor of Health Economics and Policy at the Harvard School of Public Health and an Academic Affiliate of Greylock McKinnon Associates, a consulting and litigation support firm. She holds a Ph.D in Health Policy from Harvard University and has consulted in numerous litigation matters concerning the pharmaceutical industry. Rosenthal Decl. ¶¶ 1-4.

programs, and coinsurance – and make other concerted efforts to incentivize consumers and their physicians to choose lower-cost drugs such as generics. Citing economic literature and theory, Dr. Rosenthal asserts that "when generics enter the market, a large portion of brand prescriptions are substituted by [sic] the less expensive generics resulting in significant savings relative to the pre-generic entry period." Id. at ¶ 27.

Dr. Rosenthal claims that these market principles were at work in the tacrolimus market and that delayed generic entry resulted in higher prices for class members and higher profits for Astellas. She proposes the use of "yardstick" methodology to demonstrate what would have occurred had Sandoz been able to launch its generic product on April 15, 2008 instead of in August 2009.[25] Under the yardstick approach, actual prices and quantities in the target market are compared with prices and quantities in a similar market untainted by anti-competitive activity; in this case, the comparison market is the actual market for tacrolimus *after* generic entry. Dr. Rosenthal utilized nationwide retail sales data from IMS Health, a vendor of pharmaceutical industry data, to calculate average prescription prices for both Prograf and generic tacrolimus for every quarter in the class period. She then constructed yardsticks based on what occurred in the tacrolimus market following actual generic entry and applied them to past data to simulate prices, prescriptions, market share, and other factors that would have existed in a "but-for" world. For example, observing a

[25] The "yardstick" approach is a commonly used method of economic analysis in antitrust cases. See, e.g., IIA Phillip E. Areeda, et al., Antitrust Law, at 388 (3d ed. 2007); In re Flonase Antitrust Litigation, 284 F.R.D. 207, 233 (E.D. Pa. 2012); In re Wellbutrin XL, 282 F.R.D. at 140.

12.5-percent price difference between the average retail prescription price of Prograf in the quarter just prior to actual generic entry in August 2009 and the average retail prescription price of the (cheaper) generic just after entry, Dr. Rosenthal applied a 12.5-percent reduction to the average price of Prograf around the but-for generic entry date of April 2008 to estimate a but-for price of the generic drug for that following quarter.

From this yardstick analysis, Dr. Rosenthal concludes that, absent Astellas' alleged misconduct, generic tacrolimus would have quickly captured up to 45.5 percent market share between April 2008 and December 2009, and that but-for generic prices would have been lower than the actual Prograf prices throughout that period. She likewise finds that but-for prices of Prograf would have been lower than actual Prograf prices for three of the seven quarters in the same period.

Dr. Rosenthal's report also notes that the number of PAP and VC prescriptions increased substantially after the launch of generic tacrolimus in the actual world, possibly the result of a strategic effort by Astellas to keep patients on Prograf. Dr. Rosenthal posits that had generic entry occurred earlier, these increases would likewise have occurred earlier. She therefore modeled the number of increased PAP and VC prescriptions that would have occurred in the but-for world and included their estimated value in her overcharge analysis.

Compiling various calculations, Dr. Rosenthal estimated aggregate overcharge damages for both "foreclosed generic switchers," class members who paid for Prograf in the actual world but would have purchased or reimbursed for the cheaper generic in

the but-for world, and "brand loyalists," those who paid for Prograf in both the actual and but-for worlds, but would have paid less for the brand in the but-for world.[26] Using percentages derived from national survey data about health plans, formularies, and average co-pay/co-insurance amounts, Dr. Rosenthal further allocated these overcharges among uninsured consumers (who paid for their prescriptions in full), insured consumers (who paid a co-pay or co-insurance), and TPPs.[27] She concludes that class members were injured economically by Astellas's foreclosure of generic entry through the fourth quarter of 2009, after which the overcharge damages end.[28]

b. Astellas's Objections

Astellas takes issue with numerous aspects of Dr. Rosenthal's report and counters with declarations from Dr. Pierre-Yves Cremiuex, an economist expert, and Kristin Fox-Smith, a healthcare billing and reimbursement expert.[29] According to

[26] Although Dr. Rosenthal initially referred to "brand loyalists" as "class members," she later clarified in her rebuttal declaration that the term as used in her analysis actually pertains to *prescriptions*, i.e., a "brand loyalist" is a prescription that remained branded even after generic entry. Thus, any given class member could have both "generic switcher" and "brand loyalist" prescription purchases in the but-for world.

[27] Dr. Rosenthal's calculations also include Medicare Part B copayments.

[28] Dr. Rosenthal's end date for overcharge damages conflicts with the December 2010 end date of plaintiffs' proposed class period.

[29] Dr. Cremieux is a Managing Principal of Analysis Group, Inc., an economics research consulting firm, and an Adjunct Professor in the Economics Department at the University of Québec at Montréal and the Yale School of Management. He received his Ph.D. in economics from the University of California, Berkeley, and has worked extensively on health economics, pharmacoeconomics, and antitrust issues. Cremiuex Decl. (Docket # 257, Ex. HH) ¶¶ 1-2.

Kristin Fox-Smith has worked 19 years in the pharmaceutical billing and health plan sectors of the healthcare industry, particularly with respect to transplant patients. She is currently the Reimbursement Manager at Indiana University Health and the principal of Reimbursement Solutions, LLC, in which capacity she consults with hospitals and health systems throughout the United States on healthcare billing and reimbursement issues. Fox-Smith Decl. (Docket # 257, Ex. GG) ¶¶ 1-2.

Astellas, Dr. Rosenthal's analysis fails to show that all members of the putative class were injured due to the alleged delay in generic entry, and, in fact, many were not.

To begin, both Astellas's experts contend that Dr. Rosenthal's use of average pharmacy prices and average co-payment and co-insurance terms present a skewed picture of what individual consumers and TPPs actually pay for tacrolimus. Because Prograf is priced on a per-milligram basis, the price of a prescription depends not only on the number of capsules, but also on the dosage strength. Cremieux Decl. ¶ 22. The dosage strengths prescribed to a tacrolimus patient hinge on various factors (including race, age, type of transplant, time since transplant, etc.) and may change depending on medical need. Thus, prescription prices vary significantly across patients and for individual patients over time. Id. at ¶ 23. Prescription data from 2008-2010 confirms this reality, revealing a wide distribution of per-prescription prices for both Prograf and generic tacrolimus. Pharmacy prices for both versions ranged from under $100 to over $1,500, with no tight "bell curve" around the average prices of that period. Id. at ¶¶ 24 and 110, Exs. 3.A. and 3.B. While the average Prograf prescription price is $608, 25 percent of prescriptions are priced below $242 and 25 percent are above $856; the average prescription price of generic tacrolimus is $520, but 25 percent of prescriptions are below $198 and another 25 percent are above $702. Id. Astellas claims, then, that "average" prices are inaccurate reflections of the actual range of tacrolimus prices and cannot be used to assess the fact or extent of overcharge injury.

Astellas points out similar flaws in the way Dr. Rosenthal accounts for how consumers and TPPs pay for prescriptions. While uninsured patients generally pay in

full for their prescriptions out-of-pocket, insured consumers and TPPs "share" the cost of prescriptions in accordance with the specific policies and design features of their health plans. Fox-Smith Decl. ¶ 34. Patients contribute to the cost of a prescription by paying a co-payment (a set dollar amount) or co-insurance (a percentage of the pharmacy price). Id. at ¶ 37-38. Drugs eligible for reimbursement by a particular health plan are listed on the "formulary," which is often organized into "tiers" dictating different levels of coverage. Id. at ¶ 35. Drugs in the lowest tier, where most generics are categorized, require the lowest member co-payment or co-insurance; drugs in higher tiers correspond with higher patient contributions. Id. Even for drugs on the same formulary tier, co-payment and co-insurance requirements may vary greatly under different health plans offered by the same TPP. Id. at ¶ 37-38.

Accordingly, Fox-Smith claims that the average co-payment and co-insurance terms used by Dr. Rosenthal "obscure huge variations in pharmaceutical benefit design and payment structures for Prograf during the relevant time period." Id. at ¶ 16. Transplant patients are insured by thousands of different commercial and governmental drug benefit plans, each with its own unique terms, and many patients receive financial assistance from third-party sources, maintain secondary or tertiary insurance coverage, and change prescription drug plans during the course of their treatment. Id. at ¶¶ 16-17, 32. There are also a variety of complex contractual relationships between TPPs and other entities which make it difficult to determine which entity ultimately paid for a prescription and whether or not it bore any overcharge. Id. at ¶ 17. Given this context, Fox-Smith opines that determining what a particular class member would have paid for

generic tacrolimus or Prograf at any given time during the class period would require individualized analysis of consumer prescription and payment history and the details of relevant insurance plans, including information about coverage limitations, co-payment/co-insurance terms, prescription drug formularies, and any front-end deductibles, out-of-pocket maximums, or benefit caps. Id. at ¶¶ 46-48.

Due to such variations in prescription costs, purchasing behavior, and insurance plan terms, Astellas asserts that it is not possible to determine through common proof whether a class member's per-prescription expenditures would have differed between Prograf and generic tacrolimus purchases, or between the actual world and the but-for world. Even if the average pharmacy price of Prograf in the actual world were higher than the but-for prices of Prograf and generic tacrolimus at a particular time, a consumer or TPP may not have paid any overcharge on a given prescription depending on health plan design and prescription history. Using longitudinal pharmacy claims data from Wolter-Kluwers ("WK"),[30] Dr. Cremieux illustrates such scenarios and argues that the class as defined contains large subsets of "uninjured" members.

Dr. Cremieux first highlights two important factors that distinguish this case from other generic entry situations and make injury to class members less likely. Generic drugs are typically priced significantly below their branded equivalents (on average 40 to 50 percent lower within the first year after market entry) and quickly overtake sales of the branded drug. Cremieux Decl. ¶¶ 18, 19, 21. Dr. Rosenthal also notes these

[30] The Wolters Kluwers data covers 35 to 40 percent of all tacrolimus prescriptions filled through retail and mail order pharmacies in the United States from January 2003 to September 2012.

patterns in her report, asserting that "retail price discounts for generic drugs one year after launch may be as much as 25% relative to the brand" and that "it is not uncommon for a generic drug launched today to capture 80-90% market share within 6 months to a year." Rosenthal Decl. ¶ 25. But in the case of Prograf, neither trend materialized. Cremieux Decl. ¶¶ 8, 20, 21. The average pharmacy price of the generic was only about 9 percent lower than that of Prograf for the first year after generic entry in the actual world. Id. at ¶ 21, Ex. 2. Similarly, the but-for generic prescription prices calculated by Dr. Rosenthal are only about 12 to 15 percent lower than her but-for Prograf prescription prices. See Rosenthal Decl. Att. C.3.a (Column 8) and C.3.b. (Column 8). Prograf also maintained an unusually high share of total tacrolimus prescriptions after generic entry, keeping more than half of the market one year later. Cremieux Decl. ¶ 20, Ex. 1. Dr. Cremieux explains that these idiosyncracies indicate that a large number of tacrolimus patients were "brand loyal" even after generic entry; patients who switched to generic tacrolimus ("generic switchers") did not realize the kinds of savings that patients typically realize when generic entry occurs; and the small price difference between Prograf and the generic could be captured by either the patient or the health plan according to drug coverage terms, but often not by both, meaning some TPPs actually paid more for tacrolimus after generic entry than they did before. Id. at ¶ 8. Such conclusions are significant because they suggest that many class members were not injured.

For instance, Dr. Cremieux claims that many brand loyal patients were actually harmed by or indifferent to generic entry because of their health plans' treatment of

Prograf's formulary tier status. Id. at ¶¶ 57-58. Consumers whose health plans moved Prograf to a higher tier on the drug formulary after generic entry – a common practice used to incentivize patients to switch to generics, see Fox-Smith Decl. at ¶ 39 – were thereafter subject to higher co-pays or co-insurance for their Prograf prescriptions. Cremieux Decl. ¶ 57, Ex. 8.A.1. Other brand loyal consumers saw no change in their tacrolimus costs upon generic entry because their plans kept Prograf on the same formulary co-pay tier. Id. at ¶ 57. Based on empirical analysis of the WK data, Dr. Cremieux estimates that 45 percent of brand loyalists in the data set paid more for tacrolimus and an additional 12 percent of brand loyalists experienced no change in their expenditures as a result of generic entry. Id. at ¶ 57, Ex. 5. These brand loyalists would not have paid less for their tacrolimus prescriptions had generics been available earlier and were therefore not harmed by any alleged delay.

Dr. Cremieux also maintains that large numbers of "generic switcher" consumers were uninjured by delayed generic entry. He notes that not all generic switchers switched to the generic drug immediately after it became available; many continued to purchase Prograf for a period of time before switching to the generic, and others switched back and forth between Prograf and generic tacrolimus. Id. at ¶ 60. Dr. Cremieux posits that, even assuming these patients would have made such switches earlier in a but-for world, fact of injury will depend on the timing of their Prograf and generic purchases and the specific details of their drug benefit plans. Id. at ¶¶ 59-60, 62. Like brand loyalists, generic switchers may have paid more for their Prograf prescriptions after generic entry because of formulary shifts. Id. at ¶ 62. If those higher

brand expenditures outweighed the savings occasioned by generic purchases, some of these switchers paid more, on average, for their tacrolimus prescriptions following generic entry than prior to it. Id.[31] Dr. Cremieux provides several examples of individual generic switchers (including both named consumer plaintiffs, Carrasquillo and Paone) who paid more on average for tacrolimus after generics entered the market. Id. at ¶¶ 63-68, Exs. 9.A.1-4. He finds that approximately 29 percent of all generic switchers represented by the WK data would not have been better off in the but-for world because their average tacrolimus expenditures increased following generic entry. Id. at ¶ 62.

Another subset of "unharmed" class members identified in Dr. Cremieux's analysis consists of patients whose health plans provide for capped annual expenditures. Some health plans limit patients' annual out-of-pocket prescription costs to a fixed dollar amount, beyond which their co-payment or co-insurance share would drop to zero. Id. at ¶ 69; Fox-Smith Decl. ¶ 44. Thus, patients who hit the cap will pay the same amount annually for all the drugs they purchase, regardless of whether they buy Prograf or generic tacrolimus.[32] Assessing whether these consumers were injured

[31] Moreover, although Dr. Rosenthal purports to exclude "flat co-pay" consumers from her analysis by factoring out patients enrolled in plans with a "single tier formulary design where consumers pay a fixed copay regardless of whether the drug is generic or brand," Rosenthal Decl. ¶ 52, Dr. Cremieux points out that it is possible for beneficiaries of plans with tiered cost-sharing formulas to also have the same co-pay for Prograf and generic tacrolimus. This occurs because some multi-tier plans require no patient expenditures for either brand or generic tacrolimus prescriptions and because some plans may "shift the brand to a higher tier and place the generic at the brand's old tier position on the formulary." Cremieux Decl. ¶¶ 54, 106.

[32] According to Fox-Smith, "transplant patients are more likely to reach their out-of-pocket cap than the average population because of the large number of drugs they typically take and their high drug costs." Fox-Smith Decl. ¶ 44.

would require evaluating the timing and expense of all their prescription drug purchases, of both tacrolimus and other drugs, to determine whether they would have still reached the cap had generic tacrolimus been available earlier. Cremieux Decl. ¶ 70. Dr. Cremieux estimates that approximately 3 percent of brand loyalists and 2 percent of generic switchers tracked in the WK data were uninjured by generic delay solely due to expenditure caps. Id. at ¶ 70, Ex. 5.

Dr. Cremieux also asserts that many TPPs in the proposed class were not injured by the alleged delay in generic entry. Depending on plan-specific features, a TPP's expense per prescription may actually increase when a consumer switches from Prograf to generic tacrolimus. Where a switch results in a decrease in patient expenditures (e.g., a lower co-pay) that outweighs the decrease in the pharmacy price between the brand and the generic, TPPs are left with a higher net cost. Id. at ¶¶ 81-83. In such scenarios, Prograf will be less expensive for the TPP than the generic, and the TPP is not injured by delayed generic injury. Id. Dr. Cremieux claims this is exactly what would have happened to plaintiff NMUFCW in the but-for world. Using plan and purchase data, Dr. Cremieux conducted an analysis of NMUFCW's payments with respect to the tacrolimus prescriptions of its beneficiaries. Under NMUFCW's plan, patients paid 20 percent of the cost of Prograf prescriptions, but nothing for generic prescriptions. Since the reduction in price between Prograf prescriptions and generic prescriptions was less than the reduction in the beneficiaries' share from 20 percent to zero, NMUFCW paid more on average for generic tacrolimus than it did for Prograf following generic entry. Id. at ¶¶ 85-87, Ex. 15.A-15.B.5. Given the relatively modest

price difference between Prograf and generic tacrolimus, Dr. Cremieux predicts that similar circumstances are likely for other TPPs in the class and identifies several TPPs from the WK data that also paid more for generic tacrolimus than for Prograf after generic entry. Id. at ¶¶ 92-93, Exs. 16B, 17. He notes, however, that such determinations cannot be conducted on a class-wide basis, but instead would require analysis of individualized plan-level data. Id. at ¶¶ 88, 94.

Finally, Dr. Cremieux contends that Dr. Rosenthal's impact methodology suffers from numerous flaws. Id. at ¶¶ 100-127. He argues that her analysis relies improperly on average prices per prescription and fails to account for important factors that affect what consumers and TPPs actually pay for prescriptions, including differences in the specific features and requirements of patients' pharmaceutical drug plans. Id. at ¶¶ 110, 113. He also criticizes her imposition of a damages "floor" in her calculations – counting "negative" overcharges as "zero" overcharges in instances where members of the class may have been better off as a result of generic delay – claiming that this approach overstates the aggregate harm to the class. Id. at ¶ 117. Moreover, the vast majority of Dr. Rosenthal's overcharge damages to brand loyalists (80 percent) rests on an assumption that the increase in PAP prescriptions following generic entry would have occurred earlier in the but-for world. Id. at ¶ 120. Dr. Cremieux argues that such calculations unfairly inflate the damages because the expansion of PAP eligibility in late 2009 and 2010 was not linked to generic entry, as Dr. Rosenthal assumes, but was a measure taken by Astellas in light of the high U.S. unemployment rate at that time. Id.; see also Declaration of John Liu (Docket #257, Ex. II) ¶ 10.

At bottom, Astellas and its experts insist that plaintiffs' approach fails to adequately demonstrate the fact or extent of injury to class members and misidentifies numerous uninjured class members as injured. Astellas concludes that common questions do not predominate here because class-wide impact, or lack thereof, can only be assessed through onerous individualized inquiry.

c. Analysis

I find that plaintiffs have not demonstrated predominance on the element of antitrust impact. Plaintiffs must provide the court with "enough information to evaluate preliminarily whether the proposed model will be able to establish, without the need for individual determinations. . . which consumers were impacted by the alleged antitrust violation and which were not." In re New Motor Vehicles, 522 F.3d at 28. Dr. Rosenthal's analysis, while it purports to demonstrate harm to the class as a whole, does not show injury to each of its members – that is, her methodology fails to show that all (or nearly all) class members paid supra-competitive prices for Prograf or generic tacrolimus, or that this determination can be made with common proof.

Dr. Rosenthal's reliance on average prescription prices to model the impact of delayed generic entry is problematic. A "prescription" of tacrolimus is not a standard unit of the drug; it indicates no set number of capsules or quantity of milligrams. Indeed, prescriptions for Prograf and generic tacrolimus vary widely in dosage and price, a fact obscured by the "average" prescription prices Dr. Rosenthal used to construct her but-for world. Dr. Rosenthal's pricing yardsticks are derived from observed differences in the average prescription prices of Prograf before and after

generic entry, and between the average prescription prices of Prograf and generic tacrolimus. Yet such differences are not always indicative of any actual discrepancy in the price of tacrolimus itself; they may reflect, instead, changes in the overall quantity or dosage of the drug being prescribed.

Averaging also "glides over what may be important differences" among the class. In re Graphics Processing Units Antitrust Litigation, 253 F.R.D. 478, 494 (N.D. Cal. 2008). The American Bar Association has warned of the pitfalls of using averages to show impact:

> Sometimes the prices used by economists are averages of a number of different prices charged to different customers or for somewhat different products. Using such averages can lead to serious analytical problems. For example, *averages can hide substantial variation across individual cases, which may be key to determining whether there is common impact*. In addition, average prices may combine the prices of different package sizes of the same product or of somewhat different products. When this happens, the average price paid by a customer can change when the mix of products that the customer buys changes — even if the price of no single product changed.

ABA Section of Antitrust Law, Econometrics: Legal, Practical, and Technical Issues 220 (2005) (emphasis added). As previously described, there is substantial variance not only in the pharmacy prices and dosages of tacrolimus prescriptions, but also in how benefit plans allocate the cost of a tacrolimus prescription between patient and insurer, in the timing of drug purchases, and in the costs actually incurred by individual class members. Other courts have rejected the use of averages in econometric analyses where it masks wide variations in the class. See, e.g., Allied Orthopedic Appliances, Inc. v. Tyco Healthcare Group L.P., 247 F.R.D. 156, 167 (C.D. Cal. 2007) ("[S]ensor

prices operate according to a widely varying distribution, so the average price for any particular sensor only furnishes part of the picture. . . This gives the Court little basis to conclude that the average price of generics sets some sort of evidentiary standard by which it may be decided that all or virtually all purchasers of [brand-name] sensors were overcharged "); Reed v. Advocate Health Care, 268 F.R.D. 573 (N.D. Ill. 2009) (holding that plaintiffs' use of averages "unacceptably masks the significant variation" in the compensation of registered nurses); In re Graphics Processing, 253 F.R.D. at 493-97 ("While averaging may be tolerable in some situations, the record here shows that it has in fact masked important differences between products and purchasers").

Even if the averages accurately reflected tacrolimus prices (e.g., if prices per prescription were less varied and formed bell-shaped curves around the average), plaintiffs' model does not show that Astellas's alleged misconduct resulted in higher prices than would have occurred in the but-for world. Dr. Rosenthal asserts that "prices for Prograf were higher than generic prices would have been absent the foreclosure" and that "branded Prograf prices were higher than they would have been if generic tacrolimus had launched earlier." Rosenthal Decl. ¶ 14. But while her analysis demonstrates the former, it fails to show the latter. Dr. Rosenthal's own calculations indicate that but-for Prograf prices would have been, on average, *higher* than actual Prograf prices during four of the seven quarters in her antitrust damages period. Rosenthal Decl. Att. C.3.b. Brand loyal purchases in the actual world during those quarters, then, were priced lower rather than higher than in the but-for world, and to a degree that outweighs Dr. Rosenthal's calculated overcharges for the remaining three

quarters. Id. Similarly, data from the last two quarters of 2009 show that actual world prices of generic tacrolimus were less on average than the estimated but-for price of generics for the same time period, meaning that at least some generic purchases during those quarters were likewise not subjected to any price inflation. Id. at Att. C.3.a. More importantly, quantifying differences in average prescription prices does not, by itself, adequately demonstrate class-wide injury in this case. Assuming that average prices for prescriptions of Prograf and generic tacrolimus would have been less in the but-for world than the average prescription price of Prograf in the actual world, that would not automatically mean that all the members of the proposed class suffered an overcharge for their purchases. See Sheet Metal Workers Local 441 Health & Welfare Plans v. GlaxoSmithKline, No. 04-5898, 2010 WL 3855552, at *30 (E.D. Pa. Sept. 30, 2010) ("Just because an average price was increased or decreased by the alleged foreclosure does not mean that all members of the proposed class paid supra-competitive prices..."); Reed, 268 F.R.D. at 591 ("Measuring average base wage suppression does not indicate whether each putative class member suffered harm from the alleged conspiracy. In other words, it is not a methodology common to the class that can determine impact with respect to each class member."). Observed disparities in average prices do not necessarily translate into a corresponding picture of what a class member actually paid. This is because, as Astellas's experts explain, the cost that a consumer or TPP incurs for a tacrolimus prescription is not simply a function of the drug's pharmacy price, but is dependent on the unique requirements and features of specific drug benefit plans. Dr. Cremieux identified numerous subsets of class

members, both consumers and TPPs, that presumably would not have been harmed by increased prices due to plan-specific variables, including co-payment and co-insurance policies, formulary structures, and patient expenditure limits.

In rebuttal, Dr. Rosenthal faults Dr. Cremieux for making actual-to-actual comparisons instead of conducting a but-for analysis, thereby arriving at incorrect conclusions. Rosenthal Reb. Decl. ¶¶ 23-24. Her criticism on this point is well-taken; Dr. Cremieux's analysis compares data in the actual world before and after generic entry – he does not calculate but-for prices and compare them to actual prices prior to generic entry. Dr. Rosenthal notes that when an appropriate but-for yardstick analysis is conducted on NMUFCW claims data, it becomes clear that NMUFCW did pay more in the actual world than it would have in the but-for world on the majority of its claims and in aggregate.[33] Id. at ¶¶ 25-26, Att. C. Dr. Rosenthal also claims that Dr. Cremieux's comparison of average payments before and after generic entry for individual TPPs is flawed because he relies on incomplete sample data from WK. Id. at ¶ 24. She asserts that Dr. Cremieux's comparisons are "worthless" because he "does not know how many claims are missing from the before and after period and what prices were paid for those claims." Id. at n.23.[34]

[33] In his surrebuttal report, Dr. Cremiuex conducts yet another analysis of NMUFCW's claims using Dr. Rosenthal's yardstick methodology, but with an "updated" but-for generic entry date of September 2008, which Astellas claims plaintiffs have adopted. Dr. Cremieux concludes that, under this adjusted analysis, NMUFCW was not harmed. Cremieux Sur-rebuttal Decl. (Docket # 278, Ex. A) ¶¶ 9, 22.

[34] The parties also fiercely debate the correct definition of antitrust impact. According to plaintiffs,"every indirect purchaser who made a purchase at a supra[-]competitive price" suffers injury, regardless of whether the same indirect purchaser benefitted from the generic delay on other purchases during the class period. Pl. Rep. Br. at 13. Plaintiffs insist that it is irrelevant whether a particular class member would have paid more, on average, for tacrolimus prescriptions in the but-for world than in the

Despite such apparent defects in Dr. Cremieux's methodology and sample analyses, the issues Astellas raises about uninjured class members and the need for individualized inquiries are nonetheless valid. "Even assuming the plaintiffs can show on a basic level that prices for both generic and branded [drug] increased as a result of [defendant]'s allegedly anti-competitive conduct, they must also demonstrate that *all* end-payor purchasers made a purchase at a supra-competitive price." Sheet Metal Workers, 2010 WL 3855552, at *26. Dr. Rosenthal's analysis simply does not make this showing.[35] It appears that not every prescription of Prograf sold during the class

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actual world, so long as there is at least one instance of actual overpayment. Thus, Dr. Rosenthal treats any "negative" damages as "zero" damages in her initial analysis. Rosenthal Reb. Decl. ¶¶ 29-30.

Astellas, in contrast, argues that assessing a class member's true but-for position includes accounting for "both the positive *and* negative injury arising from the alleged antitrust misconduct." Astellas's Sur-Reply Br. (Docket # 278) at 2. It claims that where a class member received reduced prices for some transactions that outweigh any overcharges for other transactions during the same damages period as the result of the same alleged violation, the resulting offset means that class member has suffered no antitrust injury.

I am inclined to agree with Astellas on this point of contention. See, e.g., Kottaras v. Whole Foods Market, 281 F.R.D. 16, 25 (D.D.C. 2012) (rejecting impact analysis that aggregated losses from antitrust conduct without crediting gains and finding that "benefits must be offset against losses"); Los Angeles Memorial Coliseum Com'n v. National Footbal League, 791 F.2d 1356, 1367 (9th Cir. 1986) ("An antitrust plaintiff may recover only to the 'net' extent of its injury; if benefits accrued to it because of an antitrust violation, those benefits must be deducted from the gross damages caused by the illegal conduct."); Blair & Page, "Speculative" Antitrust Damages, 70 Wash. L. Rev. 423, 430 (1995) ("The principal of individual net harm guides the definition of the plaintiff's actual and but-for conditions. . . . When an illegal practice harms the plaintiff in one way but benefits the plaintiff in another, the two effects must be offset."); Areeda, Antitrust Violations Without Damage Recoveries, 89 Harv. L. Rev. 1127, 1136 (1976) (noting "the necessity of offsetting injuries which plaintiffs may have suffered at the hands of defendants with benefits which they may have derived from the very activities they attack."). It matters little, however, because I find that plaintiffs here have not even demonstrated that every class member did make a purchase at a supra-competitive price.

[35] Dr. Rosenthal states that she was instructed by counsel that plaintiffs "do not need to present a methodology to identify each and every Class member," Rosenthal Reb. Decl. ¶ 14, and thus her analysis demonstrates the impact of alleged misconduct only on the class as a whole, without regard to whether every class member actually suffered harm. Rosenthal Reb. Decl. ¶ 16 ("My calculations accurately capture all the transactions in question regardless of which entity is entitled to claim damages for them."); Rosenthal Dep. at 19 (conceding that her determination of aggregate injury does not identify injury as to any particular class member).

The court in In re K-Dur Antitrust Litigation, No. 01-1652 (JAG), 2008 WL 2660723 (D.N.J. Mar. 27, 2008), another antitrust suit alleging delayed generic entry, rejected a similar approach to showing antitrust impact. There, indirect purchaser plaintiffs sought to certify a nationwide class of consumers

period was more expensive (based on pharmacy price) than its but-for counterpart. See Rosenthal Decl. Att. C.3.a and C.3.b (showing higher but-for prices for Prograf and tacrolimus in some quarters). And, as even plaintiffs and Dr. Rosenthal acknowledge, not every prescription of Prograf purchased during the class period, even at higher pharmacy prices, imposed an actual overcharge on the class member(s) who paid for it. See, e.g., Rosenthal Deposition (Docket # 257, Ex. C) at 24 ("In the sense of an overcharge model, there may be class members whose overcharge was zero . . . "); Id. at 127-28 (conceding that brand loyal consumers whose health plans move Prograf to a higher tier after generic entry would pay a higher co-payment in the but-for world, leading to a "negative overcharge"); Rosenthal Reb. Decl. n.30 ("I recognize that consumers who pay fixed copayments for the brand in both the actual and but-for worlds would not have paid a lower copay in the but-for world."); Id. Att. C. (showing "negative" damages for NMUFCW on some tacrolimus purchases during the class period). Yet plaintiffs' impact methodology provides no way of confirming, upon common proof, that every member of the class is connected to at least one higher-priced prescription, let alone whether each class member actually paid any overcharge

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and TPPs who purchased or reimbursed for the brand-name drug. As with Prograf, the small difference between the price of the branded drug and its generic alternative meant that, depending on co-pay structures, some TPPs likely paid more for the generic than for the branded drug. Variable co-pays also affected whether some consumer class members had suffered any overcharge injury. In light of these difficulties, plaintiffs advanced a "joint purchase" theory of impact, claiming injury to all class members who jointly paid part of the supra-competitive retail price of the brand drug, "irrespective of whether the portion of the price paid by particular consumers or TPPs was actually higher than the portion of the price they would have paid for the generic version." Id. at *10. The court declined to find predominance on impact, finding that the joint purchaser theory lacked precedence and was at odds with class certification decisions which specifically excluded potential plaintiffs who could not demonstrate individual injury. Id. at *13.

and was therefore injured.[36] Discerning the existence of such impact is impossible without the use of individualized data. See Sheet Metal Workers, 2010 WL 3855552, at *26 ("If only some end-payors paid increased prices, this would suggest the plaintiffs will have to prove economic impact customer-by-customer."); In re Hydrogen Peroxide Antitrust Litigation, 552 F.3d 305, 314 n.12 ("Generally, when the prices for some customers are going up while the prices of other customers are not, there is reason to doubt that the different customers (class members) are experiencing a common impact.") (quoting ABA Section of Antitrust Law, Econometrics 210 (2005)).

Plaintiffs argue that "'a class will often include persons who have not been injured by the defendant's conduct,' and 'such a possibility or indeed inevitability' does not prevent certification." Pl. Rep. Br. at 17 (quoting Kohen v. Pacific Inv. Management Co., LLC., 571 F.3d 672, 677 (7th Cir. 2009)). While that may be true, "a class should not be certified if it is apparent it contains a great many persons who have suffered no injury at the hands of the defendant." Id. at 677. I agree with Astellas that there is a substantial likelihood that significant numbers of class members did not suffer any injury given the wide variability of prescription prices, purchasing behavior, and insurance plans across the class. Plaintiffs have not shown that their methodology

[36] Overcharges associated with the hypothetical expansion of Astellas's PAP and VC programs in the but-for world, while relevant for calculating aggregate damages, are unhelpful in establishing class-wide injury because the increased subsidies are applied to some brand loyalist prescriptions as opposed to all class members across the board. See Rosenthal Decl. Att. C.3.b and C.3.e (calculating number and value of prescriptions that would have been covered by both programs in the but-for world). That is, increased PAP or VC subsidies would not necessarily have had an effect on class as a whole (only some, not all, patients who made post-entry Prograf purchases would have benefitted under either program), so the inclusion of their "lost" value in the consumer overcharges does not show that every class member was harmed.

demonstrates widespread harm to class members in spite of these distinctions, or that such a determination can be made upon common proof. Cf. In re Flonase, 284 F.R.D. at 224-226 (plaintiffs' expert tested the robustness of his methodology by conducting a "sensitivity analysis" that took into account distinctions in plan provisions, and he found that, even using extreme values, diverse class members were still harmed). Accordingly, I find that plaintiffs have failed to establish that common questions will predominate over individual ones on the issue of antitrust impact. The class cannot be certified.

3. Superiority

Superiority looks to whether "a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). Pertinent factors include class members' interests in individually controlling their own litigation; the extent and nature of any existing or pending litigation concerning the controversy; the desirability of concentrating the litigation of claims in the particular forum; and the likely difficulties of managing a class action. See Fed. R. Civ. P. 23(b)(3)(A)-(D). Plaintiffs assert that class treatment here would allow for efficient prosecution of many plaintiffs' common claims without the unnecessary duplication of evidence, effort, or expense. They argue that individual class members' claims are too small, and their resources too few, to justify bringing separate complex antitrust lawsuits against a large and well-armed opponent. Without class certification, plaintiffs warn that "Astellas's conduct will go unchallenged and Class members will go uncompensated." Pl. Br. at 36.

These are meritorious arguments, since the "core purpose of Rule 23(b)(3) is to vindicate the claims of consumers and other groups of people whose individual claims would be too small to warrant litigation." Smilow, 323 F.3d at 41. However, as previously discussed, proof of plaintiffs' antitrust injury and damages in this action will depend on individual issues rather than common ones. In such circumstances, myriad individual adjudications would render the case unmanageable. See 2 Newburg on Class Actions § 4:74 (5th ed. 2013) ("[M]any courts that find common predominance lacking, also hold that the prevalence of individual issues renders the case unmanageable for superiority purposes."). I therefore find that class action is not the superior form of litigation to resolve plaintiffs' claims.

IV. Conclusion

Plaintiffs' motion for class certification (Docket # 153) is DENIED.

Plaintiffs' motion for leave to file excess pages on their memorandum in support of class certification (Docket # 152) is ALLOWED. Astellas's motions for leave to file a sur-reply and surrebuttal report in opposition to class certification (Docket ## 277 and 278) are ALLOWED.

December 17, 2013
DATE

/s/Rya W. Zobel
RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE